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1616

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Please find below and/or attached an Office communication concerning this application or proceeding.

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DETAILED ACTION

Receipt of Request for Continued Examination and Amendments/Remarks filed November 17, 2005 is acknowledged. Claims **1-5, 7-8, 10-21, and 23-24** are pending in this application. Claims 6, 9, 22, and 25-27 stand cancelled.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 11/17/05 has been entered.

Claim Rejections - 35 USC § 102

The rejection of claims 1-3, 6-8, 10, 15-18, and 20-25 under 35 U.S.C. 102(e) as being anticipated by US patent 6,231,900 to Hanke is withdrawn in view of the amendments of 11/17/05.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 7-8, 10-11, 15-18, 20-21, 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanke (6,231,900).

Hanke teaches a confectionary product for soothing sore throat and relief of symptoms associated with cough and cold. The product is administered as a throat drop or lozenge, which releases the actives upon sucking in the oral cavity. See abstract and column 1, lines 10-20. Hanke teaches the use of a separate and distinct region for a flavor composition and a cooling composition. The cooling agent taught is any agent that provides a physiological cooling effect. See column 2, lines 55-57. The flavoring composition can be chosen from flavoring oils or essences. Flavoring liquids include cinnamon oil, artificial, natural, or synthetic fruit flavors such as citrus oil including lemon, orange, pineapple, etc. The flavoring agent may be utilized in an amount of 0.1-4%. See column 7, lines 5-26.

In a preferred embodiment, the cooling composition comprises an acidulating agent, which is an organic acid such as tartaric acid or preferably citric acid. Hanke teaches that the precise level will depend on the raw materials used and the consistency required. Suitable levels are from about 0.3% to about 1.5%, preferably from about 0.4% to about 1.3%, more preferably from about 0.5% to about 1.2% by weight of the cooling composition. Varying the level of the

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acidulating agent allows control of the dissolution/disintegration rate of the cooling composition and permits differentiation of the release profile of the cooling agent relative to that of the flavor from the flavor composition. See column 6, lines 1-20. Hanke teaches that when the confectionery product takes the form of a gelatin or gum arabic pastille, and the flavor and coolant compositions have substantially the same carrier, the compositions can be adapted to provide different release profiles by using different levels of acidulating agent in the flavor and coolant compositions. The level of acidulating agent controls the solubility and disintegration rate of the composition; the higher the level of acidulating agent in a given composition (the flavor or coolant composition), the faster the composition will disintegrate in the mouth and result in early release of the flavor or coolant. Thus, the level of acidulating agent by percent weight of the flavor composition may be greater or lesser than the level of acidulating agent by percent weight of the coolant composition. See column 8, lines 1-24.

The carriers are sugar or sugar-free bases. The sugar base is selected from sucrose, fructose, glucose, or corn syrup and the sugar-free base is selected from sorbitol or xylitol. See column 5, lines 55-63 and column 6, lines 45-50.

The examples utilize a sweetened gelatine mixture comprising 7.1% gelatine, 26.1% sucrose, 44.6% glucose syrup, and 22.2 water. Example 1 discloses the two separate compositions wherein A contains 97.8% of a sweetened gelatin mixture, 1.4% citric acid, and 0.6% of an orange flavor (lipid since Hanke utilizes a flavor oil). Composition B contains 99% of a sweetened gelatin mixture, 0.7% citric acid (acidulent), and 0.1% menthol (cooling compound). Hanke discloses the use of a mold in which the respective composition is placed and

each composition has a surface on the exterior of the product. The amount of sucrose and glucose in the composition is approximately 69%.

Hanke does not exemplify the acidulent (citric acid) in a higher concentration in the coolant composition.

Firstly, it should be noted that composition A, Hanke's flavor composition, reads on the instantly claimed oral comfort region comprising a lipid since Hanke teaches the use of a flavor oil in this region. Further, the "orange flavor" in composition A is a flavor oil since Hanke makes a distinction between "flavors" which Hanke teaches as citrus oils and "essences". See column 7, lines 10-20. Composition B, the coolant composition, reads on the instantly claimed salivation region, which contains the acidulent. Further, the claims recite open-ended claim language, i.e. comprising, the "acidulent" may be in both regions with the proviso that the respective agent is concentrated in the given area. In the exemplified formulation, the flavor composition has a higher concentration of the acidulent; however it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Hanke and utilize the acidulent in a higher concentration in the coolant composition. One would have been motivated to do so since Hanke teaches that varying the level of the acidulating agent allows control of the dissolution/disintegration rate of the cooling composition and permits differentiation of the release profile of the cooling agent relative to that of the flavor from the flavor composition. Thus, Hanke teaches that a higher level of acidulating agent provides a composition that disintegrates more rapidly in the mouth resulting in earlier release of the flavor or coolant. Therefore, it would have been prima facie obvious to utilize a higher concentration of acidulent in the coolant composition if one desired to have the coolant release earlier than the

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flavor composition. Further, although Hanke prefers that the flavor composition comprises a higher concentration of the acidulent, disclosed examples and preferred embodiments do not constitute a teaching away from the broader disclosure or nonpreferred embodiment". In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971).

With regard to claims 4-5, although Hanke utilizes a sugar base, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Hanke and utilize a sugarless base. One would have been motivated to do so with an expectation of similar results and success since Hanke teaches the carrier may be a sugar or sugarless base. Therefore, the substitution of the exemplified sugar base with the instant sugarless base is prima facie obvious.

With regard to claim 11, although example 1 teaches the flavor oil in the amount of 0.6%, column 7 suggests incorporating the flavor in an amount of 0.1-4%, which overlaps the instant range of 1-20%. The manipulation of the concentration of the flavor in view of the guidance provided by Hanke is prima facie obvious. One would have been motivated to manipulate the amount of flavor oil utilized depending on the potency of the flavor desired. Further, it should be noted that generally difference in concentrations do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such as concentration is critical. See In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

With regard to claim 20 directed to a method of treating xerostomia, it is the examiner's position that the preamble is implicitly met since the prior art discloses the same method steps of administering a confectionary product comprising two distinct areas of an oral comforting region

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and a salivation region to the oral cavity to the same population (those with throat irritation, which is a symptom of xerostomia).

Response to Arguments

Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection. However, the examiner has retained Hanke as prior art under obviousness and thus the pertinent arguments will be addressed below.

Applicant argues that the amended claims require that the salivation region comprise an acidulent as the salivation agent and Hanke teaches the opposite. Applicant argues that Hanke teaches the citric acid in a higher concentration in composition B, the flavor composition. Applicant argues that although Hanke utilizes flavor oil, the examiner does not provide any reason why the flavor oil would be utilized in an amount effective to lubricate, coat, or moisten the oral cavity.

Applicant's arguments filed 11/17/05 have been fully considered but they are not persuasive. The examiner notes applicant's amendment and acknowledges that the amendment overcome Hanke as a 102 reference. However, it is the examiner's position that Hanke renders the instant invention obvious for the reasons states above. Hanke states that the acidulent serves to control the rate of release of the flavor agent and coolant wherein a higher acidulent concentration in a given region provides the release of the desired agent first. Thus, a skilled artisan would have been motivated to utilize a high concentration of the acidulent in the coolant composition if one desired the release of the coolant earlier than the flavor. The examiner further points out that the claims only require that the acidulent is concentrated in one region and is not uniformly distributed. Thus, the claim language allows for the incorporation of an acidulent in

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both regions with the caveat that one area must have a higher concentration of the acidulent/oral comfort agent. Hanke teaches this proviso wherein Hanke clearly teaches that one region comprises a higher concentration of the acidulent than the other region.

With regard to the flavor oil, the examiner points out that the instant specification states that the effective amount of the lipid is 1-20% and Hanke teaches the flavor oil in the amount of 0.1-4% wherein Hanke's range overlaps with instant range. Thus, the flavor oil is taught in a concentration that is *capable* of lubricating the oral cavity. Further, although the example utilize 0.7%, the motivation to manipulate the concentration is provide by Hanke disclosure itself, wherein Hanke clearly states that 0.1-4% of the flavor oil may be used. One would have been motivated to utilize the maximum 4% of Hanke's range if one desired a strong flavor. It should be noted that in an obviousness rejection, the examiner's motivation to modify a reference does not need to be that of the applicant's.

For the reasons above, Hanke is considered to render the instant invention *prima facie* obvious.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 6,231,900 to Hanke (6231900) in view of US patent 6,099,880 to Klacik et al.

As set forth above, Hanke discloses preparation of a confectionary product to relieve sore throat and cough containing a separate and distinct region for a flavor composition and a cooling composition. Hanke discloses the use of a mold in which the respective compositions are placed. (Note example 1)

The reference does not teach a mold having a ridge to separate the components.

Klacik et al discloses a patterned candy containing agents such as sugar, sugar alcohol, coconut oil, and flavors. Klacik et al teach the mold having separate region and depositing mixtures in each segment to form a product with visually distinct regions. Klacik teaches this method is a simple method of forming distinct regions. See column 1, lines 30-50.

It is would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the Hanke and Klacik et al and utilize a mold with a ridge. One would have been motivated to do so since Klacik et al teach an economical and simple process of producing a product having distinct regions using a mold having a ridge. Therefore, it is obvious to utilize a ridge to further maintain the separation and distinction of each respective region.

Response to Arguments

Applicant argues that Klacik does not overcome the deficiencies of Hanke. Applicant argues that Klacik does not teach an acidulent or a salivation region.

Applicant's arguments filed 11/17/05 have been fully considered but they are not persuasive. The merits of Hanke have been discussed above and it is the examiner's position that Hanke renders the instant invention prima facie obvious. The examiner further points out that Klacik is not relied to teach an acidulent or a salivation region since Hanke is not deficient in this sense. Klacik is relied upon for its specific teaching of utilizing a mold with a ridge. The applicant has not argued the merits of this rejection is particular and thus it is the examiner's position that claim 19 is rendered obvious over Hanke in view of Klacik.

Claims 1-5, 7-8, 10-14, 17, 20, and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 5,284,659 to Cherukuri et al in view of WO 99/579427 to Le et al.

Cherukuri et al disclose encapsulated flavor with bioadhesive properties. The compressed confectionary provides controlled release of the flavor and a unique mouthfeel by using bioadhesives. The compressed tablet is characterized by discrete phases contained within. See Figure 5 and 6 wherein both phase 1 and 2 have a surface on the exterior of the product.

The compressed tablet include: (a) a first flavor ingredient present in an amount from about 0.1% to 0.5% by weight of a hydrophilic composition with which it is intimately bound to provide instantaneous delivery of the active ingredient; and (b) a second flavor ingredient present in an amount of from about 3% to 30% by weight of a hydrophobic encapsulating composition containing a bioadhesive so as to provide delivery of the second flavor ingredient over a period of time while both the tablet and encapsulated flavors adhere to the moist areas of the oral cavity.

The confectionary compressed tablet is made of a sugar or sugarless base. See column 8, lines 66-67 and column 10, lines 40-45. Sugars taught include sucrose, glucose, dextrose, fructose, and sugar alcohols include sorbitol, mannitol, and xylitol. See column 9, lines 7-21. Emulsifiers (surfactants) are taught in an amount of 2-7%. See column 8, lines 40-55.

Cherukuri also teaches that in addition to encapsulated flavor ingredients, a bio-effecting agent such as breath fresheners, breath deodorants, antigingivitis agents, and combinations thereof may also be used. See column 7, lines 30-45.

Table II, example III discloses a product wherein the shell component contains 97.676% sugar, 0.748 % of a breath deodorant (copper gluconate), 0.234% lubricant, 1.280% flavor beads, 0.062% liquid flavor. This shell region reads on instant "salivation region" since this region contains the bio-effecting agent (the breath freshener). The core comprises 40.32% fat encapsulation material of Table I and 59.68% of a diluent. Table I discloses a fat encapsulation

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containing 48% partially hydrogenated soybean oil, 5% glycerol monostearate, 10% vegetable oil, 2% flavor oil, and 20% bioadhesive. This core region read on instant "oral comfort region". Cherukuri teaches the diluent may be selected from lactose (sugar), microcrystalline cellulose, starch, talc, sorbitol, mannitol, xylitol, maltitol, xylitol, other sugar alcohols or sugars. See column 8, lines 60-65. Note that this diluent reads on applicant's confectionary base of the oral comfort region. The tablet is made by mixing each respective composition with the respective components separately and then the core is compressed into the shell portion. See column 10, line 40 to column 11, line 28.

Although Cherukuri teaches the use of bioeffecting agents in the shell portion, Cherukuri does not teach the specific use of an acidulent in the shell portion.

Le teaches co-processed comestible, confectioneries, pharmaceuticals, and dentifrices comprising an acid and water-soluble crystalline compounds. Le teaches that the prior art conventionally uses acidulents in comestible for a variety of reasons. For instance, acidulents may be used to increase saliva production for the treatment of xerostomia and dry mouth; the use of acids to soften plaque on teeth; as flavor enhancers to improve the release of flavor in confectionary products such as hard candies. See page 1. Le teaches the acidulent may be inorganic or organic acids including phosphoric acid, citric acid, malic acid, succinic acid, fumaric acid, ascorbic acid, etc. see page 5, lines 13-25. The acidulent is utilized in an amount of 0.2% of the entire composition (note example 4 in combination with Table 2 formulation wherein the acidulent is 5.5% of the coprocessed formulation and the coprocessed formulation is 3.75% of the composition)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Cherukuri et al and Le et al and utilize an acidulent as the bio-effecting agent in the shell portion of Cherukuri's composition. Firstly, one would have been motivated to do so with a reasonable expectation of success since Cherukuri teaches the use of bio-effecting composition in the composition; thus a skilled artisan would have been motivated to utilize an acidulent in Cherukuri's example as the bio-effecting agent in place of the breath freshener if one desired to treat xerostomia and dry mouth rather than halitosis. Secondly, one would have been motivated to utilize an acidulent in the shell portion since Cherukuri teaches the shell portion provides the release of the first flavor (the rapid release portion) and thus a skilled artisan would have been motivated to utilize an acidulent in the shell portion since Le teaches acidulents are conventionally utilized to improve and enhance the release of the flavor. Therefore, a skilled artisan would have been motivated to utilize an acidulent in the shell portion to increase the rate of release of first flavor in the hydrophilic portion (shell portion).

With regard to claim 14, the manipulation of the concentration of emulsifier in the core composition of example III is considered to be obvious to one of ordinary skill. The examples utilize a range of 5%, however one would have been motivated to utilize the instant range of 0.5-4% since Cherukuri teaches the emulsifier may be utilized in a range of 2-7%. Therefore, the range taught by Cherukuri overlaps the instant range.

Art of Interest

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US patent 4,847,090 to Della Posta et al disclose a confection piece with two or more discrete areas to provide a unique organoleptic response. However, Della Posta does not teach

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each region having the instant oral comforting components and the instant salivating agents respectively.

Conclusion

All the claims are rejected at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Sharmila S. Gollamudi
Examiner
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